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Eva Raschke

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EXAMINER

KELLY, ROBERT M

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 09/844,662  
Filing Date: April 27, 2001  
Appellant(s): RASCHKE ET AL.

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Dahna S. Pasternak  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed 9/8/2009 appealing from the Office action mailed 4/17/09.

**(1) Real Party in Interest**

The PTO no longer allows the Examiner to comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

**(2) Related Appeals and Interferences**

The examiner is not aware of any additional related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

**(3) Status of Claims**

The following is a list of claims that are rejected and pending in the application:

Claims 57 and 68-71.

**(4) Status of Amendments After Final**

The PTO no longer allows the Examiner to comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

**(5) Summary of Claimed Subject Matter**

The PTO no longer allows the Examiner to comment on the summary of claimed subject matter contained in the brief.

**(6) Grounds of Rejection to be Reviewed on Appeal**

***Claim Rejections - 35 USC § 112 – NEW MATTER ALONE***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 57 and 68-71 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, for being drawn to new matter. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

***Claim Rejections - 35 USC § 112—NEW MATTER AND WRITTEN DESC***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 57 and 68-71 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement and the new matter portion of written description. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the Appellant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the Appellant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the Appellant for patent, except that an

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international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 57, 68, 70, and 71 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,013,453 to Choo, et al., Patented 11 January 2000, claiming priority to 1994.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 57 and 68-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,013,453 to Choo, et al., Patented 11 January 2000, claiming priority to 1994, and WO 00/9837755 to Dangl, et al.

### **(7) Claims Appendix**

The PTO no longer allows the Examiner to comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

### **(8) Evidence Relied Upon**

6013453

CHOO

1-2000

Dangl, J.L. "Plant Pathogen Response Gene" WIPO Publication (Sep 3, 1998), whole document.

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**(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

***Claim Rejections - 35 USC § 112 – NEW MATTER ALONE***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 57 and 68-71 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, for being drawn to new matter. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 57 and 68-71 are complexes in cells, in which a generic zinc finger comprising at least 3 fingers, one of which recognizes a generic non-naturally occurring finger is bound to cellular chromatin in a region sensitive to digestion with DNase I.

There is simply no implicit or explicit description in the original claims and/or specification to demonstrate that Appellant had considered such genera to be the invention.

While there is generic description of modified fingers, recognizing modified sequences, and the use of DNase I digestion (it is noted again this is a non-limitation as the region is so broad as to encompass a whole chromosome), no Artisan could reasonably envision that Appellant interpreted such to be in the invention. The reliance on various portions of the claims and/or specification as originally-filed therefore, only provides support in the form of

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obviousness. However, obviousness does not supplant the need to disclose to the Artisan the invention in a form that demonstrates possession. Obviousness is not possession.

***Claim Rejections - 35 USC § 112—NEW MATTER AND WRITTEN DESC***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 57 and 68-71 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement and the new matter portion of written description. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Appellant's claims encompass a generic **non-naturally occurring** zinc finger protein comprising 3 or more zinc finger domains.

The specification teaches generally to mutate known domains, but does not teach the structure of all zinc finger proteins, nor does it teach what mutations are non-naturally occurring. Still further, the original claims and the original specification fail to demonstrate any possession of the genera as claimed. At best, non-naturally occurring amino acids are claimed to be an inclusive genera in the overall genera of the invention (e.g., paragraph 0073 of the Application Publication), however such fails to evince that Appellant possessed only those with non-naturally occurring amino acids, as a genera, much less the larger genera of any non-naturally-occurring

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zinc finger protein, as the discussion is simply a large laundry list of different types of modifications, and not an evincing of specific possession of any particular genera.

Further, while the Art teaches many zinc finger proteins, the Examiner has been unable to find any evidence that all zinc finger protein structures are known, nor has the Examiner been able to find evidence that there are known structures of zinc finger domains which cannot occur in nature.

Hence, the Artisan could not determine Appellant to have been in possession of such a generic zinc finger protein at the time of filing, and therefore, the claims are lacking proper description.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the Appellant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the Appellant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the Appellant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 57, 68, 70, and 71 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,013,453 to Choo, et al., Patented 11 January 2000, claiming priority to 1994.

Choo teaches, in Example 4, the making of a mutant Zinc finger protein, which has 3 fingers, and binds to the coding sequence for a specific ras mutation which commonly occurs and



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causes oncogenesis. Choo teaches that the mutant Zinc finger can be used to bind the mutant ras gene in human cells in research (Id.).

Moreover, absent reason to believe otherwise, this site occurs within the broad definition of a general region which is in some way sensitive to digestion with DNaseI.

Hence, the claims are anticipated.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 57 and 68-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,013,453 to Choo, et al., Patented 11 January 2000, claiming priority to 1994, and WO 00/9837755 to Dangl, et al.

Choo teaches making mutant Zinc Finger libraries, which are displayed on the surface of a particle (e.g., ABSTRACT). Choo teaches that such zinc finger libraries may be used to make mutant Zinc finger protein domains that bind novel sequences by screens (e.g., Summary of the Invention). Such zinc finger proteins can be used to bind genomic DNA (e.g., Id.). Moreover, at least one mutant zinc finger binding domain contains at least 3 zinc fingers (Example 5).

However, Choo does not teach plant cells.

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On the other hand, Dengl demonstrates that zinc fingers occur, and regulate pathways (e.g., ABSTRACT). Therefore, it is a truism that zinc fingers also work in plant cells.

Hence, it would have been obvious at the time of invention to modify Dengl's methods and libraries to bind plant genomic DNA, and then utilize such to modify the expression of sequences of DNA. The Artisan would have done so because Choo teaches the ability to do so, and the motivation to study, e.g., point mutations, e.g., from Example 6. Moreover, the Artisan would have a reasonable expectation of success, as Choo teaches that such possible, and Dengl demonstrates that zinc fingers work in plant cells.

Moreover, Appellant is reminded that the breadth of "region" and "sensitive" are so broad as to cause the limitation to have no meaningful significance.

#### **(10) Response to Argument**

Prior to the full response to the arguments, it is noted that Appellant's Brief is defective. 37 CFR 41.37(c)(vii) recites, *inter alia*, "Each ground of rejection must be treated under a separate heading." Appellant has argued the separate rejections for new matter and new matter/written description under a single heading. The Examiner will address the pertinent argument in each case under the specific basis of rejection provided by the Examiner, as arguing both rejections together can only lead to confusion, and increase the likelihood of mistakes in judgment.

#### ***Claim Rejections - 35 USC § 112 – NEW MATTER ALONE***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 57 and 68-71 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, for being drawn to new matter. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

To briefly explain the rejection provided, the rejection is based on the aspect of a generic 3-fingers or more in the zinc finger, wherein at least one zinc finger domain comprises a non-naturally occurring recognition helix, bound to a generic region which is sensitive to DNaseI digestion. To wit, the limitations of at least 3 fingers, wherein one or more finger comprises a non-naturally occurring recognition helix, bound to a region which is DNaseI digestion, is a generic aspect which is not found to have been possessed at the time of filing.

Appellant argues that they have attempted to amend the claims to remove non-naturally occurring, in a sincere effort to advance prosecution (p. 5, paragraph 1).

The Examiner does not argue this point, but the amendment was proposed after-final, and such amendment would cause the Examiner to have to perform further examination, but, being after-final, such further prosecution is not allowed. Still further, non-naturally occurring is the whole basis of this rejection, but it is the generic 3-fingers, one of which comprises a non-naturally occurring region, bound to a region that is sensitive to DNaseI digestion.

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Appellant argues that the proposed amendment after-final is allowed, that support need not be literal, and that the specification provides such information, when taken in context of the Art, to know what is meant by non-naturally occurring (pp. 7-8).

Such is not persuasive. The rejection is based on the presence of 3 zinc fingers being present, and that one of the fingers contain a non-naturally occurring recognition helix, and it is bound to a region which is sensitive to DNaseI. The genera excludes less than three fingers, and specifically claims that in any of 3 or more fingers, at least one is non-naturally occurring, and further it is required to be bound in a generic region sensitive to DNaseI digestion. Appellant's disclosure as originally filed does not provide sufficient disclosure to evidence possession of such generic embodiment. What Appellant is attempting to get at is a claim to those that are designed or selected, as can be seen from their arguments after-final, and the Arguments to which Appellant has referred are arguments that Appellant has not defined the term "non-naturally occurring" to mean those that have been designed or selected (E.g., Advisory Action of 6/25/09). While such appears to more directly apply to the other rejection for new matter and written description, it is addressed here as the term "non-naturally occurring" is part of the rejection language. Non-naturally occurring, as evidenced in such arguments of 6/25/09, was clearly there to mean that non-naturally occurring is not commensurate with fingers which have been designed or selected, but is something that is non-coextensive. Lastly, to state this clearly, the term "non-naturally occurring" was not, and has not been, rejected for a lack of clarity in its scope (i.e., 35 USC 112, second paragraph); what has been argued is that Appellant's support is found, at best, in terms of those sequences which have been made by selection or design; however, the rejection is made further in the context that the fingers are limited to three or more,

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and only one finger being required to have a non-naturally occurring helix domain, bound to a region which is sensitive to DNaseI digestion. Being selected for, or being designed in laboratory, is not the same as non-naturally occurring, and further, the support for the generic number of fingers, minimum of one non-natural domain, and bound to a generic region sensitive to DNaseI digestion is simply not possessed. This is further exacerbated by the fact that argument in itself fails to address the rejection being made herein.

To make this explicitly clear, it appears that is confusing the term “non-naturally occurring”, in that the present rejection here is to the number of fingers, one comprising a non-natural sequence for recognition, bound to a site in a region which is sensitive to DNaseI digestion. Appellant’s fingers may be disclosed as generic to containing fingers, or to comprising non-naturally occurring recognition sequences, but the genera that 1 region is non-naturally occurring, within three finger is simply a random choice within the larger scope, made to overcome art rejections. There is no evidence of possession at the time filing, but a choice made during prosecution, and hence, possession is at best evidenced during prosecution, and after filing. The rejection basis, although encompassing non-natural sequences, does not solely rely on the fact of what is non-naturally occurring.

Appellant cites several portions of the specification, and specifically paragraph 158 of the specification to argue that the Artisan would know the structure of a non-naturally occurring sequence (pp. 6-8), in such recitation.

The Examiner does not find this persuasive. The description is generic to all zinc fingers, and not those of three fingers, one finger of which, at a minimum comprises a non-naturally-occurring sequence, and binds to a region which is sensitive to DNaseI digestion. Appellant

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has simply chosen a sub-genera within their larger scope described, and therefore believes it is possessed. Possession requires specific contemplation, whether evidenced by indirect evidence (e.g., a lack of contemplation of anything else or a specific contemplation of all embodiments outside the claimed scope and within a larger contemplated scope) or literal support.

Appellant argues that the board has already decided that even when the term “naturally occurring” does not appear in the specification, it would clearly be understood by the Artisan to mean those that exists or are found in nature (p. 9, paragraph 3).

Such is not persuasive. Appellant is confusing written description and new matter with that of clarity under 35 USC 112, second paragraph. Clearly such is not argued by the Examiner, as there is no such rejection.

Appellants argue that the vast amount of art present for zinc finger proteins including non-naturally occurring helicies is not relevant (p. 9, penultimate paragraph-p. 11, paragraph 3).

Such is not persuasive. While it would be proper to respond with a recitation as to where in prosecution such argument was made, as there are currently 195 prosecution documents, it appears from the argument made that the Examiner was arguing that those that are present are not relevant to the rejection, because it is not on the basis of non-naturally occurring, per se, but due to the scope of number of fingers, only one comprising a non-naturally occurring region, and bound to a region which is sensitive to DNAase I digestion.

To recap, the basis of rejection is to a generic finger, with three fingers or more, one of which contains a non-naturally occurring recognition sequence, and bound to a region which is sensitive to DNaseI digestion.

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***Claim Rejections - 35 USC § 112—NEW MATTER AND WRITTEN DESC***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 57 and 68-71 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement and the new matter portion of written description. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

To summarize, this rejection is based on the fact that those sequences which are non-naturally occurring, and those zinc fingers which are non-naturally occurring have not been defined in structure sufficiently to evidence that Appellant possessed the genera of non-naturally occurring.

Appellant argues that they have attempted to remove “non-naturally occurring” but it was not entered, as the Examiner stated that such would raise issues of new matter and require a new search (p. 5, paragraph 1).

Such is true, but fails to make the important point. As has been stated in, e.g., the Official Action of 4/17/09, various subjects touch on the point of non-naturally occurring. One of those subjects is the point of non-naturally occurring amino acids. Appellant's removal of such limitation in such context requires a consideration of those non-naturally occurring zinc finger proteins with the 3 or more fingers, wherein one contains a non-naturally occurring recognition helix. The question is, by removing the initial recitation of “non-naturally

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occurring” with respect to “zinc finger protein comprising 3 or more zinc finger domains, wherein the zinc finger domains comprise a non-naturally occurring recognition helix” (quoted from the proposed amendment of 6/10/09 which yielded the Advisory argument of 6/25/09, which made the statement of consideration required), would require a consideration of how, by removing what it is called, affected its structure, and whether or not the various forms of “non-natural” are encompassed by the new scope of limitations, and whether or not those that are encompassed are supported to form a new, theoretical, sub-genera from what was previously claimed. As Appellant’s argument is made, however, it seems as if Appellant is arguing that the Examiner was not acting in good faith, and just obfuscating prosecution. Such is not what has happened, as Appellant left out mentioning the other limitation of non-natural in the same claims. Clearly this is what the Examiner was referring to in the advisory action which lead Appellant’s quotations.

Appellant argues that many helicies are known in the Art, and some are naturally occurring, while others are non-natural and that they have disclosed several embodiments, quoting those passages, as well as how to make them (pp. 7-9).

Such is not persuasive. What Appellant is described is a method to make, but such does not disclose to the Artisan which sequences will be non-natural, and which will not, nor does it disclose the generic structure of a non-naturally-occurring zinc finger, and how it differs from a naturally-occurring sequence. In fact, it is a truism that until all zinc fingers are sequenced, allowing the Artisan to screen them, there is simply no way to tell whether any particular sequence occurs in nature or not.



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Appellant also “strongly traverse” the assertion that the vast art regarding zinc finger proteins that include zinc fingers with non-naturally occurring helicies is not relevant to the rejection (pp. 9-11).

Such is not persuasive. Until a generic structure is identified, or it is known, for the vast majority of zinc finger helicies which occur, or a deductive set of non-natural sequences are disclosed, it cannot be possessed as a genera. What Appellant possesses is a genera of methods to make zinc fingers, screen zinc fingers, and shuffle zinc fingers; They do not possess non-naturally occurring sequences.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the Appellant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the Appellant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the Appellant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 57, 68, 70, and 71 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,013,453 to Choo, et al., Patented 11 January 2000, claiming priority to 1994.

Appellant argues that in response to an assertion that Choo does not necessarily and inevitably teach that their zinc finger proteins form a complex with a region of chromosomal cellular chromatin that is sensitive to DNaseI digestion, it was asserted by the Examiner that

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Choo is not required to state that they did it, but only teach that it can be done (p. 11, last paragraph, citing the Advisory Action of 6/25/09-p. 12, paragraph 2).

Such is not persuasive. Appellant misquotes Choo out of context. As was stated, Choo specifically demonstrates by Experiment that cellular chromatin can be so-bound, by utilizing integrated genes, and the paragraphs following the quotation demonstrate that it can be bound, demonstrating it to be enabled. Therefore, it is clear that the Examiner's statement was one that was arguing that Choo enabled the invention for binding chromosomal DNA. In fact, Appellant's selective quotations of the record also fail to provide the citation that the Examiner stated, with respect to these same arguments "However, such argument is selective reading of the example, which must be taken in context. In fact, the same example demonstrates that this question is overcome, by performing experiments to demonstrate that it can bind cellular chromatin. In fact, further on, after a consideration of the results in the same Example 3, Choo States "In summary, the inventors have demonstrated that a DNA-binding protein designed to recognize a specific DNA sequence in vitro, is active in vivo where, directed to the nucleus by an appended localization signal, it can bind its target sequence in chromosomal DNA."" (Advisory Action of 6/25/09). With regard to the arguments to inherency, etc., Appellant is again taking the context out of everything and simply presenting it in a light that is not untrue, but very misleading.

Appellant argues that the appealed claims are drawn to a complex where the zinc finger is necessarily and inevitably bound to DNaseI hypersensitive sites in cellular chromatin (p. 12, paragraph 3).

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Such is not correct. The Claims are drawn to a “region” which is “sensitive” to DNaseI digestion, not that the zinc finger binds to a site that comprises DNaseI hypersensitive sites.

Appellant argues, again misquoting Choo’s statements out of context to binding DNA in chromatin, and arguing that the zinc finger binds to a non-endogenous DNA in experiments, that Choo did not enable binding endogenously-found DNA sequences in their normal context *in vivo* (pp. 13-14).

The examiner argues that Choo is again misquoted, out of context, and the subsequent experiments and findings of Choo specifically state the that zinc fingers can bind endogenous sequences in their normal context. In addition, there is no scientific basis for making such reasoning, its simply implication taken from misquoted statements, out of context, and fails to recognize Choo's contribution to the Art. What mechanism on earth or heaven exists to question the applicability, beyond that of fear of the unknown? Nothing. The Examiner cannot accept argument that is not based in scientific reason, but simply relies on the absence of a 102 demonstration to mean automatically the subject matter is not enabled. If that were the case, there would simply be no 103 rejections in the Art at all. It also means that there need be no reason, and mere fear, without any supporting logic or data, causes any subject matter to be non-enabled. Why would a gene, however large, including whole chromosomes, removed from one cell, then placed in another cell, suddenly allow binding of modified zinc fingers, while, as best the Examiner can determine from Appellant's argument, an unmodified zinc finger could bind both the gene from its original cell, or placed into another cell? Alternatively, if it is not the cell, but the context of being within a chromosome, out of context, why would an out-of-context gene be bound by modified zinc fingers, while the normal zinc finger, as best the Examiner can

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Appellant's argument, can bind it regardless of being in context or not? There is no reason or logic here. This is the point the Examiner has continually driven at in this case, as well as all the related appeals associated with this case. Implications, hinged on out-of-context quotes and ambiguous fears, are simply not enough to change our understanding of the Art.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 57 and 68-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,013,453 to Choo, et al., Patented 11 January 2000, claiming priority to 1994, and WO 00/9837755 to Dengl, et al.

Appellant argues rehashes previous arguments to argue that Choo's sequences are not a chromosomal sequence as claimed (p. 14, paragraph 2).

Such is not persuasive. Again, this is out of context. Example 3 of Choo demonstrates a test to determine that sequences can be bound when in the chromosome, and concludes that they can be so-bound. How Choo chose to demonstrate it is not a problem, because there is no rhyme or reason to believe that somehow, when the DNA was naturally in the chromosome, it is completely distinct from when it was inserted, such that only natural zinc fingers would bind, while modified ones would only bind the inserted sequence. Choo's conclusion to the experiment in Example 3 was to that point, stating that therefore it could bind, at the very least,

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for actively transcribing genes. Is Appellant's argument that their claim is limited to genes which are not actively transcribing?

Appellant cites Beerli and Boorman (which have not been officially considered, and were specifically not provided in an IDS to avoid any questions of whether it was officially considered, because Appellant provided them in the After-final argument without explaining good and sufficient reasons why it could not have been presented earlier) to argue that Choo is not enabled for binding natural chromatin in natural context (pp. 14-15).

Such is not persuasive. First, it should be noted that Boorman reference has not ever been considered in this case, and the Beerli reference was first utilized to argue the case in the After-final argument, but was not considered, such is a new reference or argument, respectively, which could have been provided earlier, and Appellant provided no argument as to why it was not, or could not have been argued before. However, because the Office currently no longer allows the Examiner to correct the Brief for proper format and providing for proper evidentiary consideration, the Examiner will answer the new and non-proper argument and evidence, for the first time officially: Boorman and Beerli are papers comprising authors who were inventors in the Choo patent. They do specifically state that they performed, for the first time, binding to natural sites, in natural chromatin context, in cells, after the priority date of Appellant. They do state that prior to their demonstration, "willful and specific regulation of endogenous genes with designed transcription factors has remained an unmet challenge in biology". However, there is no scientific basis to believe it would not work prior to an actual demonstration. There is no reason to know why it remained an unmet challenge in biology. Simply put, at best, it appears to the examiner that Boorman and Beerli and Choo, were busy with other things, and this is the first

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time they decided to prove it. They provide no rationale as to why it might not work, and it appears that the first time they attempted it, it worked. There is no evidence of failed experiments. If there were, there would be problems with enablement, likely even for Appellant's claimed invention. Again, the evidence is full of puffery, but lacking in substance. The Examiner, being a scientist in the biological fields, could never accept such lack of substance to supplant the need for logic and/or data to contradict the conclusion, in order to find Choo non-enabled for the claimed genera, and hence, again, the Examiner finds that the Artisan would not so-find Choo to be non-enabled for the genera of natural sequences, in natural context, on the chromosome in which was originally found, in the cell it was originally found, would not bind modified zinc fingers. There is no reason here.

Therefore, the Examiner argues that the rejections should be sustained by the board of appeals.

#### **(11) Related Proceeding(s) Appendix**

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Robert M Kelly/

Primary Examiner, Art Unit 1633

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